UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO: County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 18-OP-45090

County of Cuyahoga v. Purdue Pharma L.P., et al.

Case No. 1:18-OP-45004

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

PHARMACY DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO AMEND

Plaintiffs' motion to amend the Track 1 Third Amended Complaints to include dispensing claims represents a stunning about-face. During more than a year and a half of litigation, including fact discovery, expert discovery, full briefing of motions to dismiss, multiple summary judgment motions, and the start of trial proceedings, Plaintiffs chose to pursue *distribution* claims against the Pharmacy Defendants. Plaintiffs represented—and this Court ruled definitively—that Plaintiffs were pursuing only distribution claims and no dispensing claims against the Pharmacy Defendants. *See* Doc. No. 1203 at 2 (holding "Retail Pharmacies may only be held liable as distributors," because "Plaintiffs have disclaimed any cause of action against Retail Pharmacies in their capacity as retailers or dispensers of opioids"). Indeed, Plaintiffs candidly admitted in a recent filing that "[t]hese issues were purposefully deferred from CT1." Doc. No. 2921 at 6.

Now, suddenly, Plaintiffs want a complete do-over of their case. Eighteen months after the Court-ordered deadline for amendments to complaints, nine months after the close of fact discovery, five months after the close of expert discovery, months after rulings on various summary judgment and *Daubert* motions, and weeks after a jury was empaneled and trial began against one of the Pharmacy Defendants, Plaintiffs seek to amend their Third Amended Complaints to add the very "dispensing" claims they have repeatedly forsworn. And what is more, in claiming that pharmacists erred in reviewing and filling individual prescriptions for individual patients, Plaintiffs would add new defendants that they previously voluntarily dismissed.

Plaintiffs' new claims:

- target the conduct of completely different corporate functions and employees;
- are based on entirely different legal duties;
- require the identification and production of entirely different documents and data; and
- require reopening completed depositions and discovery and commencing depositions of numerous additional party and third-party witnesses—from pharmacists to prescribers to patients to new experts.

The Federal Rules of Civil Procedure and binding Sixth Circuit law foreclose such an extraordinary reboot of Plaintiffs' case at this late stage—all the more so given that nothing prevented Plaintiffs from bringing these claims 18 months ago. A party seeking leave to amend its pleadings after the time for amendment has expired must show under Rule 16(b) that "good cause" exists for modifying the deadlines set by a scheduling order. *See Leary v. Daeschner*, 349 F.3d 888, 909 (6th Cir. 2003) (requiring a showing of good cause for amendment to pleading after deadline set by scheduling order). An amending party must show "that despite their diligence they could not meet the original deadline," *id.* at 907, and that the opposing party "would not suffer prejudice" from the amendment, *id.* at 908 (citations omitted). Plaintiffs do not even recite these standards, much less attempt to meet them. They offer *no* reason for their woefully dilatory request. And their blithe assertion that Pharmacy Defendants would suffer no prejudice from their proposed amendments is not just self-evidently baseless; it is belied by the incredibly onerous

dispensing-related discovery demands that Plaintiffs propounded on the heels of their motion for leave to amend. This Court already has ruled in relation to another defendant that it would be "manifestly unfair" to allow Plaintiffs to re-open discovery after making a "tactical decision" not to pursue it initially. Doc. 2438 at 4 (denying additional discovery as to Noramco). There is no basis for a different ruling here.

Given Plaintiffs' recent admission that they "purposefully deferred" dispensing claims, *see* Doc. No. 2921 at 6, their efforts to add them now smacks of gamesmanship, and in any event is utterly devoid of good cause. The Court should reject Plaintiffs' motion summarily.¹

BACKGROUND

A. Chronology

Plaintiffs had every opportunity to bring dispensing claims before the amendment deadline 18 months ago and when they amended their complaints twice since. They elected not to do so. The chronology of events establishes that Plaintiffs lack "good cause," as required by the Sixth Circuit, to amend now.

April 11, 2018	CMO One issues and sets an amendment deadline of April 25, 2018.
	Doc. No. 232 at 6 (¶ 3.b). It states: "No later than Wednesday,
	April 25, 2018, Plaintiffs in Track One cases shall amend their
	Complaints" <i>Id.</i> (emphasis in original).

April 11, 2018	On the same day, the Court orders DEA to produce by April 20,
	2018, transactional ARCOS data for the Track One jurisdictions,
	among others. Doc. No. 233. The Court states that the data will
	permit plaintiffs to identify, among others, pharmacies. <i>Id.</i> 8.

April 20, 2018	DEA produces the transactional ARCOS data for the Track One
	jurisdictions. The data shows the volume of prescription opioids
	received by the Pharmacy Defendants in their <i>pharmacy</i> capacity.

¹ Pharmacy Defendants incorporate by reference our objection to the Court's apparent prejudgment of the issue, as communicated to the Pharmacy Defendants in writing by the Special Master. *See* Doc No. 2907.

April 25, 2018	In keeping with the deadline in CMO One, Plaintiffs file amended complaints. In their April 25, 2018, amendments, Plaintiffs add CVS, Rite Aid, Walgreens, and Walmart entities to their complaints, suing them as "distributor defendants" along with AmerisourceBergen, Cardinal, and McKesson. Doc. No. 301 ¶ 116.
May 18, 2018	Plaintiffs seek—and obtain—leave to amend their complaints again. The new complaints do not bring dispensing claims against CVS, Rite Aid, Walgreens, or Walmart. Rather, the amendments add more defendants, including Discount Drug Mart and HBC/Giant Eagle, again as "distributor defendants." <i>See</i> Doc. No. 477 ¶ 127.
June 19, 2018	In response to personal jurisdiction motions, Plaintiffs dismiss claims against CVS Health Corporation and Rite Aid Corporation and name instead the CVS and Rite Aid entities whose business relates to distribution for purposes of pursuing distribution claims against these defendants. <i>See, e.g.</i> , Doc No. 637. The CVS and Rite Aid entities named do not operate pharmacies in Ohio.
June 22, 2018	In connection with motion to dismiss briefing, Plaintiffs state in writing: "Plaintiffs do not allege violations of statutes and regulations applicable specifically to retailers who sell opioids." Doc. No. 654 at 75 n. 47.
Oct. 23, 2018	The Special Master makes discovery rulings based on "plaintiffs' affirmative disavowal of claims premised on dispensing practices."
Dec. 19, 2018	The Court issues an Opinion and Order that, among other things, states: "the Retail Pharmacies may only be held liable as distributors." Doc. No. 1203 at 2. The Court states that "Plaintiffs have disclaimed any cause of action against retail pharmacies in their capacity as retailers or dispensers of opioids." <i>Id.</i>
January 25. 2019	Fact discovery closes.
March 21, 2019	Summit County files a third amended complaint. Doc. No. 1466. The amended complaint does not add dispensing claims against Pharmacy Defendants.
May 10, 2019	Cuyahoga County files a third amended complaint. Doc. No. 1631. This amended complaint also does not add dispensing claims against

Pharmacy Defendants.

Close of expert discovery.

June 7, 2019

June 28, 2019

Deadline for filing summary judgment and *Daubert* motions.

July 31, 2019	After the close of fact and expert discovery and the filing of summary and <i>Daubert</i> motions, Plaintiffs move to sever from the Track One trial Discount Drug Mart, HBC/Giant Eagle, Rite Aid and Walmart. In doing so, Plaintiffs attest that severance will not be used to prejudice these defendants. Doc. No 2099 at 3.
August 7, 2019	Plaintiffs move to sever the CVS defendants. Plaintiffs again attest that severance will not be used to prejudice CVS. Doc. No 2148 at 2.
Sept. 10, 2019	The Court issues its last of many rulings on summary judgment and <i>Daubert</i> motions, including on motions filed by the Pharmacy Defendants.
Oct. 15, 2019	Final pretrial conference for non-severed defendants
Oct. 17, 2019	Jury selected and sworn in.
Oct. 21, 2019	On the morning of opening statements, after four of the non-severed defendants settle, the Court cancels the trial against the remaining defendant, Walgreens.
Oct. 29, 2019	After the passage of 18 motions, many amendments of their complaints, the completion of all discovery, and Plaintiffs' express representation that they are not pursuing dispensing claims, Plaintiffs shift course and attempt for the first time to add dispensing claims through their motion for leave to amend.

B. The Proposed New Claims

Plaintiffs previously asserted claims against the Pharmacy Defendants only for the conduct of their distribution centers in monitoring orders placed by their own pharmacies. Plaintiffs' proposed new claims, in contrast, challenge the conduct of the individual pharmacists employed by the Pharmacy Defendants in filling individual prescriptions written by individual doctors on behalf of individual patients. These are new and different claims in every possible respect—including as a matter of the governing legal obligations and facts at issue.

The regulatory provisions applicable to the new claims are entirely different. *Compare* 21 CFR §1301.74(b) (distribution centers "shall design and operate a system to disclose ... suspicious

orders") with 21 CFR § 1306.04(a) (pharmacists have a "corresponding responsibility" not to "knowingly fill[]" "a prescription issued not in the usual course of professional treatment"). The registrants responsible for the conduct at issue in the new claims are entirely different, too, since they are pharmacies instead of distribution centers. As a result, Plaintiffs seek to add new entities to the case, like Ohio CVS Stores, LLC and Rite Aid of Ohio.

The applicable data is entirely different as well. Rather than depending on records of distribution center shipments, Plaintiffs' new claims will turn on individual prescriptions filled on behalf of individual patients. The prescription-level data would dwarf in volume the distribution data that has already been produced. And for dispensing claims, the data alone does not prove anything, because aggregate proof does not suffice to establish a violation of a pharmacist's duties. See Order on Hearing Scope and Government Motions Regarding the Respondents' Experts at 8-9, In the Matter of Holiday CVS, L.L.C., Dkt. No. 12-37 and 12-38 (U.S. Dept. Of Justice, Drug Enf't Admin.) (April 13, 2012) (proof of "aggregate numbers ... shed no light on the extent to which the registrants here executed their corresponding responsibility and thus would provide no relevant evidence") [Exhibit A]. Prescription-by-prescription analysis (and discovery) is necessary.

The relevant facilities and witnesses are entirely different as well. While Plaintiffs' distribution claims focused on a handful of distribution centers, their proposed dispensing claims implicate the work of hundreds of pharmacists at dozens of locations filling innumerable prescriptions written by doctors across the region for any number of patients.

Simply put, Plaintiffs' proposed new claims would bring the case back to square one. New custodians and search terms, as well as new document and data productions, would be implicated. Scores of new depositions would be noticed by the parties—from local pharmacists to local

prescribers to patients. Depositions would need to be re-opened—from the Ohio Board of Pharmacy to DEA to local law enforcement. And a whole range of new experts and new expert reports would be required.

ARGUMENT

Plaintiffs may only be permitted to amend their complaints by showing "that despite their diligence they could not meet the original deadline," *Leary*, 349 F.3d at 907, and that Pharmacy Defendants "would not suffer prejudice" from the amendment, *id.* at 908 (citation omitted). Plaintiffs do not even attempt to meet either part of their burden. On the contrary, they plainly admit that they "purposefully deferred" dispensing claims "from CT1," *see* Doc. No. 2921 at 6. Their motion must be denied.

I. PLAINTIFFS CANNOT SHOW GOOD CAUSE FOR THEIR ABOUT FACE.

Plaintiffs' sudden and belated about-face does not remotely meet the standards set by the Federal Rules for amending pleadings. Although leave to amend "shall be freely given when justice so requires," "[i]n evaluating the interests of justice" under Rule 15(a), "courts consider several factors, including 'undue delay in filing[and] lack of notice to the opposing party." Oleson v. United States, 27 F. App'x 566, 569 (6th Cir. 2001) (citation omitted). Plaintiffs' 18-month delay—following fact discovery, expert discovery, resolution of motions to dismiss, and summary judgment briefing and rulings, and even the beginning of trial—is plainly undue.

Nor have Plaintiffs shown the "good cause" that Rule 16(b) requires for a belated amendment. *See Leary*, 349 F.3d at 907 (holding that late-amending parties must "demonstrate 'good cause' for their failure to comply with the original schedule, by showing that despite their diligence they could not meet the original deadline."); *id.* at 909 ("Once the scheduling order's deadline passes, a plaintiff first must show good cause under Rule 16(b) for failure earlier to seek leave to amend before a court will consider whether amendment is proper under Rule 15(a).").

"The primary measure of good cause is the movant's diligence in attempting to meet the order's requirements." *Rahn v. Hawkins*, 464 F.3d 813, 822 (8th Cir. 2006), *overruled on other grounds* by *Avichail ex rel. T.A. v. St. John's Mercy Health Sys.*, 686 F.3d 548, 552 (8th Cir. 2012). Plaintiffs make no attempt to establish good cause.

A. Plaintiffs Deliberately Chose Not to Plead—And Repeatedly Disavowed—Dispensing Claims.

Plaintiffs do not and cannot claim that they lacked the ability to state dispensing claims earlier in this case. On the contrary, since the inception of the litigation and throughout the last 18 months, Plaintiffs' counsel, members of the Plaintiffs' Executive Committee in the MDL, have filed innumerable lawsuits against Pharmacy Defendants, some of them asserting distribution claims, some of them asserting dispensing claims, and some of them asserting both. In this case, by contrast, Plaintiffs confirmed in response to Pharmacy Defendants' motion to dismiss that they were not asserting dispensing claims (thereby sidestepping Pharmacy Defendants' arguments against any dispensing claims). In their response to the motion to dismiss, for instance, Plaintiffs stated that they "do not allege violations of statutes or regulations applicable specifically to retailers who sell opioids." Doc. 654 at 75 n.47.

For more than a year and half, Plaintiffs unequivocally maintained their position that their Complaints state no dispensing claims against Pharmacy Defendants. They reiterated these representations in the course of discovery, and they relied on the fact that they were not pursuing dispensing claims to avoid responding to discovery asking that Plaintiffs identify the prescriptions they maintained were improper. They consistently stated that their "claims do not turn on the contention that particular prescriptions were medically unnecessary or improper," Letter from Paul Hanley to Special Master at 2 (Aug. 17, 2018) [Exhibit B], and—in a stipulation in exchange for permission not to respond to propounded discovery—reiterated that "Plaintiffs will not assert,

either in expert opinions or factual presentations at trial, that any specific prescription caused or led to harm," Doc. 1071-1 at 6.²

Plaintiffs' disavowals were the basis for rulings by this Court. In its opinion on the motions to dismiss, the Court held that the "Retail Pharmacies may only be held liable as distributors," because "Plaintiffs have disclaimed any cause of action against Retail Pharmacies in their capacity as retailers or dispensers of opioids." Doc. 1203 at 2. The Special Master also recognized, in Discovery Ruling 8, "plaintiffs' affirmative disavowal of claims premised on dispensing practices." Doc. 1055 at 3.

Even before their disavowals, Plaintiffs deliberately chose to sue entities involved in distribution and to voluntarily dismiss other entities. With their current proposed amendments, Plaintiffs seek to undo that strategic choice by adding into the case numerous defendants, including Ohio CVS Stores, LLC, Rite Aid of Ohio, Inc., and Rite Aid Corporation. One of these entities, Rite Aid Corporation, was amended into the case and then voluntarily dismissed by Plaintiffs in response to a motion to dismiss for lack of personal jurisdiction and after Plaintiffs learned that it did not engage in distribution. Moreover, on the eve of trial, Plaintiffs dismissed their claims against Walgreen Eastern Co., but they now seek to bring that entity back into their new dispensing case.

It cannot be said, then, that Plaintiffs did not know about the dispensing claims they now bring; on the contrary, they expressly disavowed them in court pleadings. Plaintiffs cannot reverse this decision simply because in hindsight—following a year and a half of fact and expert discovery and after fully preparing their cases for trial—they regret their choice.

² Plaintiffs' assertion that "Defendants prevented Plaintiffs from obtaining pharmacy level data and discovery," Mot. at 4, is both wrong (because they did obtain pharmacy-level discovery) and misleading (because any discovery constraints were the inescapable consequence of Plaintiffs' own positions).

B. Nothing Prevented Plaintiffs From Pleading Dispensing Claims Earlier.

Plaintiffs make *no* attempt to explain their 18-month delay in seeking to amend their pleadings. *See Leary*, 349 F.3d at 907 ("Plaintiffs gave the district court no excuse for their considerable delay...."). Nor is any explanation available. Nothing prevented Plaintiffs from bringing their dispensing claims by the amendment deadline. Indeed, Plaintiffs had full access to the pharmacy-level ARCOS data at the time they amended their Complaints in April 2018. And by the time of their amendments, many other municipalities—represented in many cases by the Plaintiffs Executive Committee—already had brought opioid-based dispensing claims against one or more of the Pharmacy Defendants. *See Barstad v. Murray Cty.*, 420 F.3d 880, 883 (8th Cir. 2005) (affirming denial of leave to amend where movants "knew of the claims they sought to add when they filed the original complaint").

To the extent Plaintiffs offer any excuse at all, they suggest that their amendment is warranted because Walgreens proposed to call pharmacists as witnesses at the Track 1A distribution trial, and thus "pharmacy-related evidence is likely to be at issue." Mot. at 5. This is beside the point. The fact that one Pharmacy Defendant planned to use certain evidence at a trial on distribution claims has nothing to do with whether Plaintiffs could have asserted different claims against other defendants in a timely fashion. And even if it were relevant to the inquiry, Plaintiffs cannot possibly claim to have been surprised that pharmacists would be relevant witnesses in a trial concerning whether pharmacists placed orders with distribution centers that Plaintiffs claim were suspicious. Moreover, Walgreens explained in pretrial briefing how, contrary to Plaintiffs' unsupported assertions, Plaintiffs received all of the relevant pharmacy-related discovery that they ever requested. See Doc. No. 2855 at 2-3; see also Doc. No. 2772. For all of

these reasons, Walgreens' trial witness list provides no excuse for Plaintiffs' failure to move for leave to amend to assert entirely new claims against six different defendants in a timely fashion.

II. PLAINTIFFS' PROPOSED AMENDMENTS WOULD SEVERELY PREJUDICE PHARMACY DEFENDANTS.

Even if Plaintiffs had met their burden to show good cause for their untimely amendment (and they have not), their motion to amend must be denied because it would result in extreme prejudice to Pharmacy Defendants. *See Leary*, 349 F.3d at 906 (asking "whether the opposing party will suffer prejudice by virtue of the amendment"); *see also Olseon*. 27 F. App'x at 569 (identifying "undue prejudice to the opposing party" as a consideration under Rule 15(a)). Among the factors that courts consider in assessing prejudice is "whether the assertion of the new claim or defense would ... require the opponent to expend significant additional resources to conduct discovery and prepare for trial." *Phelps v. McClellan*, 30 F.3d 658, 662-63 (6th Cir. 1994). The prejudice that the requested amendment would cause is extraordinary.

To begin with, Pharmacy Defendants relied heavily on Plaintiffs' repeated representations that they were not stating dispensing claims. On this basis, Pharmacy Defendants formulated their legal strategy and defense on the assumption that Plaintiffs meant what they said, and that dispensing claims were off the table. Moreover, Plaintiffs represented in their motions to sever that they would not use severance to "prejudice" the Pharmacy Defendants. But using severance to buy time to add new theories of liability is just that. Plaintiffs should not be permitted to retract that promise and manipulate the course of these proceedings.

Even worse, the proposed amendment would put the Pharmacy Defendants to a new and massive discovery burden. Not only would Plaintiffs add new entities and new claims, but these proposed claims involve new legal standards and a different regulatory framework. Plaintiffs themselves have already demonstrated how these new claims will require massive additional

discovery. On the same day that Plaintiffs filed their motion for leave to amend, they propounded their "(First) Combined Discovery Requests to Dispensers." [Exhibit C] The requests are shocking in their excess, particularly at this advanced stage of the litigation. Among many other things, Plaintiffs seek:

- *all* dispensing data from *all pharmacies nationwide*, including highly detailed information about each individual prescription;
- information and data dating from January 1, 1996 to the present;
- *nationwide* transactional data regarding dispensing, including the number of controlled and non-controlled substances dispensed.

It will take enormous time and incalculable resources for Pharmacy Defendants to respond to these sweeping requests—some of which run contrary to prior orders in this case concerning scope of discovery.

In addition, Pharmacy Defendants would be required to take their own discovery to defend against Plaintiffs' dispensing claims—including, among other things, discovery of local prescribing doctors and hospitals, individual patients, local pharmacy schools, the Ohio Board of Pharmacy, and DEA. *See Morgan v. Gandalf*, 165 F. App'x 425, 431 (6th Cir. 2006) (holding that opposing party was entitled to discovery following amendment by moving party).

Case law establishes that this additional discovery, without more, requires that Plaintiffs' motion be denied. *See Phelps*, 30 F.3d a 663; *Shane v. Bunzl Distribution USA, Inc.*, 275 F. App'x 535, 537 (6th Cir. 2008) ("The filing of a fourth complaint . . . would have prejudiced [the opposing party] because it would have required still further discovery."); *Leary*, 349 F.3d at 908-09 (holding that the non-moving party "can show prejudice by the fact that discovery will have to be reopened, years after it was closed, . . . if this amendment were permitted."); *Duggins v. Steak 'N Shake, Inc.*,

195 F.3d 828, 834 (6th Cir. 1999) ("Allowing amendment at this late stage in the litigation would create significant prejudice to the defendants in having to reopen discovery.").

In addition to the prejudice caused by discovery, the new dispensing claims would introduce significant new legal complications into an already-complex case. Pharmacy Defendants would be entitled to file motions to dismiss on the new claims, to reopen depositions to ask newly pertinent questions, to conduct third-party discovery, to develop new expert witnesses, to interpose new defenses, and to file new summary judgment motions.

Plaintiffs also may attempt to use their requested leave to amend to reopen discovery and cure the deficiencies in their proof on the distribution claims exposed at the summary judgment stage. Plaintiffs failed to present expert testimony regarding the suspicious order monitoring systems of four of the six Pharmacy Defendants. As explained at the summary judgment stage, this failure of proof requires summary judgment, and it is far too late in the day for Plaintiffs to cure this deficiency. Summary judgment is warranted on the distribution claims against those Pharmacy Defendants against whom Plaintiffs failed to present expert testimony, and Plaintiffs cannot evade this result by reopening discovery.

* * *

In granting Plaintiff's Severance Motion, this Court expressly rejected the suggestion that discovery could be reopened against Noramco:

Plaintiffs' Severance Motion appears to imply that were the Court to extend or stay the deadline for Plaintiffs to respond to Noramco's MSJ, that Plaintiffs would be able to take more discovery of Noramco. . . . To the extent discovery has been limited, it was limited because Plaintiffs made the tactical decision not to pursue discovery against Noramco. *Track One* discovery is complete, and Plaintiffs' choice not to pursue discovery against Noramco is one they will have to live with. For these reasons, the Court concludes that including Noramco in the subsequent trial while allowing or even attempting to allow Plaintiffs' to seek additional discovery would unnecessarily delay a subsequent trial. This would be manifestly unfair to both Noramco and the other severed defendants.

Doc. 2438 at 4. Nothing has changed since this Court's previous analysis, and the same is true here: allowing Plaintiffs to amend and thereby to seek additional discovery would be manifestly unfair to Pharmacy Defendants.

CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' Motion to Amend.

Date: November 12, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1(f)

Pursuant to Local Rule 7.1(f), I hereby certify that this Court has ordered that length limitations applicable to complex cases apply to this matter, ECF No. 232 at 4 (No. 1:17-MD-2804), and that the foregoing Reply is within Rule 7.1(f)'s page limit for a complex case.

/s/ Kelly A. Moore

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on November 12, 2019, the foregoing was filed using the Court's CM/ECF filing system and will be served via the Court's CM/ECF filing system on all attorneys of record.

/ s/ Kelly A. Moore